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### Indian Standard

# SPECIFICATION FOR SPECIAL PURPOSE SYRINGES

## PART 8 ANGIOGRAPHY SYRINGE

- 1. Scope Covers requirements of angiography syringes which are used to inject the contrast media in arteries, etc, for medical diagnosis.
- **1.1** For general requirements the provisions covered in IS: 3235-1980 'General requirements for syringes for medical use ( *first revision* )' shall apply unless otherwise stated in this standard.

# 2. Sizes and Dimensions of Syringes

- 2.1 Typical all glass syringe is shown in Fig. 1A of IS: 3236-1980 'Specification for hypodermic syringes for general purposes ( first revision )'.
- 2.2 The capacities of syringe shall indicate their sizes, which shall be in accordance with Table 1.
- 2.3 Tolerance on the graduated capacity and on any capacity greater than half the graduated capacity shall be ±4 percent.
- 2.4 Sub-division or scale intervals shall be 1 ml for all syringes.
- 2.5 The alternate graduations as shown in Fig. 1 may have long graduations extended on both sides of short graduations and may be of double the length of short graduation.
- 2.6 The length of scale, minimum length of the long graduation marks and the numbering of the scale interval shall be in accordance with Table 1.

TABLE 1 GRADUATED CAPACITY, LENGTH OF SCALE/MINIMUM LENGTH OF LONG GRADUATION MARK AND NUMBERING OF SCALE INTERVALS OF ANGIOGRAPHIC SYRINGES

Graduated Capacity of Syringes	Length of Scale	Minimum Length of Long Graduation Marks	Numbering of Scale Intervals
(1)	(2)	(3)	(4)
ml	mm	mm	
20	104 ± 6	10	5, 10, 15, 20
30	87 ± 6	13	5, 10, 15, 20, 25, 3
40	116 ± 6	13 \	5, 10, 15, <b>2</b> 0, 25, 3
40	1 <b>0</b> 0 ± 6	13∫	<b>35,</b> 40
50	125 ± 6	13	5, 10, 15, 20, 25, 3 35, 40, 45, 50
80	1 <b>40</b> ± 6	16	5, 10, 15, 20, 25, 3 35, 40, 45, 50, 55 60, <b>65</b> , 70, 75, 8

2.7 Dimensions of syringes shall be in accordance with Table 2.

### 3. Requirements

3.1 Nozzle — The Luer lock nozzle shall be situated centrally on the barrel. Luer lock connection shall be in accordance with Fig. 2 of IS: 3236-1980 and comply with the requirements and tests, given in both IS: 3235-1980 and IS: 3234 (Part 2)-1986 'Specification for conical fittings with 6 percent (Luer) taper for syringes, needles and other medical equipment: Part 2 Lockfittings ( second revision )'.

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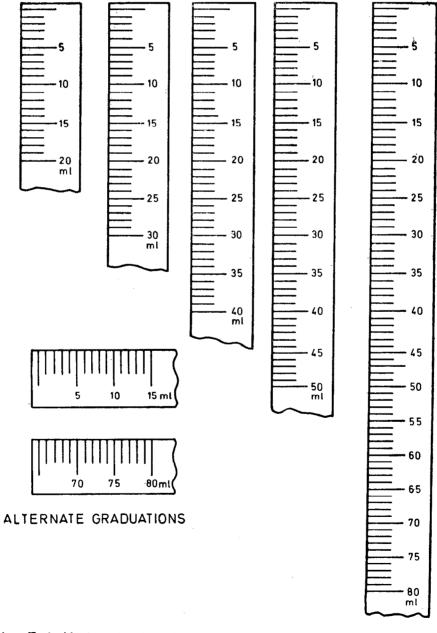
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TABLE 2 DIMENSIONS OF ANGIOGRAPHIC SYRINGES

( Clause 2.7)

Graduated Capacity of Syringes	Length of Non-Graduated Part of the Barrel of Syringe	Mininmum Length of Projection	Maximum Overall Length	Minimum Thickness of Glass
(1)	(2)	(3)	(4)	(5)
m1 20 30 40 40 50	mm 30 to 40 30 to 40 30 to 40 30 to 40 35 to 45 40 to 50	mm 15 15 15 15 15	mm 192 194 223 210 245 260	mm 1:4 1:6 1:6 1:6 1:8



Note - T ypical horizontal scale is also permitted.

FIG. 1 GRADUATIONS ON ANGIOGRAPHY SYRINGE

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- **3.2** The numbering of scale intervals shall be in accordance with col 4 of Table 1. The number shall be close to but shall not touch the ends of the graduation mark to the details given in Fig. 1. The number shall be clearly defined, durable and easily legible.
- 3.3 The piston shall be easily visible through the barrel and the fiducial line shall be capable of being judged against the graduation very accurately.
- 3.4 The effluent diameter of all syringes shall be 2.1  $\pm$  0.1 mm.
- 3.5 The Luer lock tip shall be such that the tip has a collar with internal thread to receive the corresponding needle and which when rotated shall securely hold it.
- 4. All tests as per IS: 3235-1980 shall apply.
- 5. Marking Each syringe shall be legibly and durably marked with the following:
  - a) Manufacturer's name, initials or recognized trade-mark;
  - b) Unit of capacity, ml; and
  - c) Means of identification of barrel and piston.
- 5.1 Certification Marking Details available with the Bureau of Indian Standards.
- 6. Packing Shall be as agreed to between the manufacturer and the purchaser.
- 7. Sampling Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However, a recommended sampling plan is given in Appendix A.

# APPENDIX A

(Clause 7)

#### SAMPLING PLAN AND CRITERIA FOR CONFORMITY

### A-1, Lot

- A-1.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimensions under similar conditions shall constitute a lot.
- A-1.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 3.

Lot Size	Sample Size	Sub-Sample Size
(1)	(2)	(3)
Up to 100 101 to 159 151 to 500 501 to 1 900	5 8 13 20	5 5 8 13

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TABLE 3 SCALE OF SAMPLING

A-1.2.1 These syringes shall be selected from the lot at random and in order to ensure the randomness of selection procedures given in IS: 4905-1968 'Methods for random sampling, may be followed.

#### A-2. Number of Tests and Criteria for Conformity

1 001 to 10 000

10 001 and above

A-2.1 All the syringes selected at random in accordance with col 1 and 2 of Table 3 shall be tested for dimensions, capacity, shock test, leakage test, test for entraped fluid and freedom from striae and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.

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A-2.2 If the lot is found to be conforming to the requirements given in A-2.1, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 3. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.

A-2.3 The lot shall be considered as conforming to this standard if A-2.1 and A-2.2 are satisfied.

# EXPLANATORY NOTE

IS: 3237 was first published in 1965 and revised in 1980. It had then covered hypodermic syringes of small capacity, namely, insulin syringes, tuberculin syringes and B. C. G. syringes. In the second revision of this standard undertaken in 1985, these special purpose syringes were covered in three separate parts. Subsequently, other special purpose syringes have also been added to this standard as its further parts as given below:

IS: 3237 (Part 1)-1985 Insulin syringes ( second revision ).

IS: 3237 (Part 2)-1985 Tuberculin syringes (second revision).

IS: 3237 (Part 3)-1985 B. C. G. syringes ( second revision ).

IS: 3237 (Part 4)-1986 Allergy vaccine syringes.

IS: 3237 (Part 5)-1986 Post operation care syringe.

IS: 3237 (Part 6)-1986 Irrigation syringe.

IS: 3237 (Part 7)-1986 Feeding syringe.

IS: 3237 (Part 8)-1986 Angiography syringe.